DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2005-E-0310 (previously FDA Docket No. 2005E-0245)]

Determination of Regulatory Review Period for Purposes of Patent Extension; KEPIVANCE;

Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting a notice that appeared in the <u>FEDERAL REGISTER</u> of April 2, 2007 (72 FR 15699). The document concerned FDA's determination of the regulatory review period for KEPIVANCE. The document cited an incorrect statute under which the KEPIVANCE biologics license application was submitted. This document corrects the citation.

FOR FURTHER INFORMATION CONTACT:

Beverly Friedman,

Office of Regulatory Policy,

Food and Drug Administration,

10903 New Hampshire Ave.,

Bldg. 51, rm. 6222,

Silver Spring, MD 20993-0002,

301-796-3602.

SUPPLEMENTARY INFORMATION: In FR Doc. 2007-15699 on page 15700 in the FEDERAL REGISTER of Monday, April 2, 2007, the following correction is made:

2 CDER201244

1. On page 15700, in the first column, in the first line, "505(b) of the act" is corrected to read "351 of the Public Health Service Act (42 U.S.C. 262)."

Dated: February 28, 2012.

Jane A. Axelrad, Associate Director for Policy, Center for Drug Evaluation and Research.

[FR Doc. 2012-9325 Filed 04/17/2012 at 8:45 am; Publication Date: 04/18/2012]